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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,081	03/29/2007	Qiwang Xu	33888-400200	1679

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EXAMINER	
KRISHNAN, GANAPATHY	
ART UNIT	**PAPER NUMBER**
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,081	XU ET AL.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 11/29/2007 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 1-5 have been canceled.

2. Claim 6 has been amended.

3. Remarks drawn to rejections under 35 USC 101, 112, first and second paragraphs, double patenting and 102.

Claims 6-9 are pending in the case.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The rejection of Claims 1-5 under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, has been rendered moot by cancellation of the said claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of Claims 6-9 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating psoriasis, systemic lupus erythematosus and hyperthyroidism, does not reasonably provide enablement for treating or controlling any other autoimmune disease by administering N-acetyl-D-glucosamine to a patient, as instantly claimed, has been overcome by amendment of claim 6 to recite erythematosus and hyperthyroidism.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, has been rendered moot by cancellation of the said claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of Claims 6-9 provisionally on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-6 of copending Application No. 10/550,784 ('784), is being maintained for reasons of record.

Applicants have argued that the copending claims do not render obvious the diseases recited in instant claim 6 as amended. This is not found to be persuasive.

As discussed in the rejection below, Adalsteinsson et al (WO 01/19374), disclose that in the case of autoimmune diseases activation is thought to occur after infection by common bacteria or virus and several viruses are implicated in such diseases (page 3, line 24 through page 4, line 6). Since viral infection can lead to the diseases as instantly claimed there is a suggestion for the use of the active agent to be used for treatment of both autoimmune diseases and viral infections.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of Claims 6-9 under 35 U.S.C. 102(b) as being anticipated by Burton et al (US 5,217,962) has been overcome by amendments to claim 6, which now recites method fo treatment of erythematosus and hyperthyroidism.

The following rejection is made of record necessitated by amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under

37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adalsteinsson et al (WO 01/19374) newly cited in view of Burton et al (US 5,217,962), of record.

Adalsteinsson teaches the use of a composition comprising glucosamine for the treatment of autoimmune diseases like Graves disease (same as hyperthyroidism) and erythematosus and psoriasis using glucosamine. According to Adalsteinsson rheumatoid arthritis is an autoimmune disease and its etiology is much the same as that of any other autoimmune disease (page 1, lines 13-16; page 3, line 24 through page 4, line 6; page 8, line 20 through page 10, line 3). Salt forms of the active agent can also be used (page 14, lines 9-11) and the compositions can be prepared for other forms of administration (page 21, line 16 through page 22, line 13). Adalsteinsson et al do not exemplify or teach the use of N-acetyl-D-glucosamine for the treatment of the diseases as instantly claimed. However, one of skill in the art will recognize from this teaching that an active agent containing the glucosamine moiety can also be used for the treatment of diseases like erythematosus and hyperthyroidism.

Burton et al teach the oral administration of N-acetyl glucosamine for the treatment of psoriasis (a local lesion). The dosage is about 300mg to 10,000g per day (col. 2, lines 52 through col. 3, line 3; col. 8, lines 30-46) and the active agent can be incorporated in a pharmaceutically acceptable carrier. Even though Burton does not

specifically teach the use of N-acetyl glucosamine for the treatment of erythematosus and hyperthyroidism, Adalsteinsson teaches that in addition to rheumatoid arthritis, autoimmunity often results in diseases like Graves disease (same as hyperthyroidism) and erythematosus and psoriasis (Adalsteinsson, page 4, lines 3-6). Hence, one of skill in the art will recognize from the teaching of Adalsteinsson and Burton that N-acetyl-D-glucosamine can also be used for the treatment of erythematosus and hyperthyroidism (Graves disease).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use N-acetyl-D-glucosamine or a pharmaceutically acceptable salt ca be used in a method of treatment of erythematosus and hyperthyroidism as instantly claimed since the treatment of etiologically related psoriasis has been taught I the prior art to be treated with the same active agent.

One of skill in the art would be motivated to use N-acetyl-D-glucosamine or its salts in the same method of treatment since Burton teaches that N-acetyl-D-glucosamine is a neutral compound, is stable, is soluble, tasteless and is readily absorbed from the digestive tract. It also has a half life of 4 hours and very little is excreted as it is a 'committed metabolite' and is readily taken up by the human body and utilized (col. 5, lines 30-44). One of sill in the art will recognize that these are all favorable properties of the active agent and hence, would use N-acetyl-D-glucosamine in the method as instantly claimed. It is well within the skill level of the artisan to adjust the dosage and frequency of administration based on the teachings of the prior art.

Conclusion

Claims 6-9 are rejected

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK

2/5/08

Shaojia A. Jiang
Supervisory Patent Examiner
Art Unit 1623